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AUG - 9 2005 - 1 - (3)

August 3, 2005

Mark B. McClellan, M.D. Ph.D. Administrator  
Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attn: CHS-1501-P

P.O. Box 8016

Baltimore, Maryland. 21244-8018

Dear Dr. McClellan:

The purpose of this letter is to state my  
interest in cryosurgery for prostate cancer.

As a wife and nurse of a man who  
has been successfully free of prostate  
cancer since May 2000 due to this  
procedure I know its value as an  
option to be offered.

I am responding to a notice in the  
July Federal Register that contained the  
proposed hospital outpatient payment  
rates for prostate cryosurgery procedures  
in 2006. I have been informed that  
the new proposed rate will not cover  
what hospital costs are.

The value of this procedure is  
manyfold. They include no bleeding,  
rare incontinence, rapid recovery,

0. - 0.5% fetal injury. My husband was playing tennis 2 weeks following the procedure. In addition, I should never return. This procedure can be repeated unlike seeding and radiation.

We need more doctors doing this and more hospitals to offer it.

Therefore I urge you to adjust the proposed payment rate for APC 674 upward to reflect a hospital's actual cost to perform the procedure.

Sincerely yours,

Sally McKawitz, M.S., R.N.

c.c. James L. Hart, CM5  
Mary Syick

CMD  
Pymt/Rates

2 of 2

(2)

AUG - 9 2005

August 3, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Center for Medicare & Medicaid Services  
Department of Health & Human Services  
Attn: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Hart  
Santow  
Bazell  
Kane

Dear Mr. McClellan:

This letter is in regards to CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate.

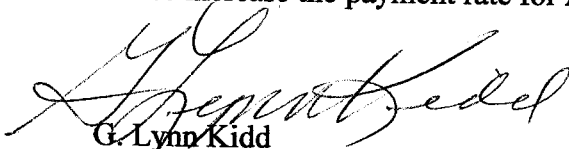
I was informed that I had prostate cancer in 2003 and that it was a slow growing cancer that progressed to moderate prostate cancer. I did not like the current treatments of Prostate cancer but when I found out about the cryosurgery procedures I had the procedure.

This was a perfect procedure for me and I know it will be for many other men who have early detection of prostate cancer.

It has come to my attention that the new proposed hospital outpatient payments for prostate cryosurgery procedures for 2006 are to be reduced and will not cover the hospitals costs. This is wrong for many reasons but mainly the Cryosurgery procedure will save money in the long term.

In my case the Cryosurgery for prostate cancer was less invasive, my hospital stay was about 8 hours in total, and certainly my recovery was more rapid than all other known procedures. The obvious cost savings with this procedure should be an incentive to increase payment rates for APC-674 so that more hospitals will offer the procedure so that more men will have access to this minimally invasive procedure.

Please increase the payment rate for APC 674!!

  
G. Lynn Kidd  
2467 Mars ave.  
Idaho Falls, Idaho 83402

1 AUGUST 2005

ADMINISTRATOR, CENTER FOR MEDICARE AND MEDICAID SERVICES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
ATTN: CMS-1501-P  
P.O. BOX 8916  
BALTIMORE,, MD 21244-8018

DEAR ADMINISTRATOR,

I WAS THE 12TH PATIENT THAT MY DOCTOR PERFORMED CYROSURGERY ON. THE DATE WAS 1993, SAME DAY SURGERY AND THAT WAS THE END OF MY PROBLEM. I STILL GET CHECKED ONCE A YEAR WITH NOTHING WRONG, PSA IS NEARLY 0. I HAD TO PAY FOR MY OPERATION AND HAVE NO REGRETS. NOW I UNDERSTAND THAT REIMBURSEMENT BY MEDICAID AND MEDICARE FOR THIS SERVICE IS GOING DOWN SO FEWER DOCTORS WILL PRESCRIBE CRYO. I FOR ONE HATE TO SEE THIS HAPPEN BECAUSE IT'S SO SIMPLE WITH NO RECOVERY TIME AND SHOULD SAVE MEDICARE MONEY. I HAVE NO MEANS OF PROVING THAT IT WILL SAVE MONEY AND I'M SURE YOU WILL CHECK IT OUT.

THANKS FOR CONSIDERING MY REQUEST.

*James C. Sargent*  
JAMES C. SERGENT

COPY TO:  
DEPUTY DIRECTOR

3-3  
Cryo  
Rymt/Rates

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AUG - 9 2005

Hart  
Sargent  
Bazell  
Kane



Valley Baptist  
Health System

2101 Pease Street  
P.O. Drawer 2588  
Harlingen, Texas 78551

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D/A  
AUG 15  
Hart  
Barrell  
Kane  
Santaw

August 8, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P.  
P.O. Box 8016  
Baltimore, MD 21244-8018

Comment on Medicare Program; Proposed Changes to the Hospital Outpatient  
Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Page 42737 "Drug Administration"

The proposed change from CPT codes to G codes for 2006 is an increased administrative burden on the hospital. Changing the codes three times in three years---from Q to CPT to G present onerous burdens on coding, clinical, and billing staff. In many cases the drug reimbursement is packaged. If the administration of the drug is not charged, the hospital receives no reimbursement. Nursing bears the burden of administering, charting, and **charging** for the administration of the drug. This burden is extreme. Surely you can devise a fair method of reimbursement that does not involve clinical staff counting hours, minutes, and number of injections. Each drug has a preferred method and time for administration which should be considered when reimbursement is calculated. There is no reason to charge the hours that a drug is infused each time it is infused for each patient. Please consider the nurse in an ambulatory infusion unit trying to track multiple patients with multiple infusions and injections.

Sincerely,

*Catherine Mezmar*

Cathy Mezmar RN, MSN  
APC Coordinator



Valley Baptist  
Health System

2101 Pease Street  
P.O. Drawer 2588  
Harlingen, Texas 78551

5 AUG 15 2005  
O-15 C/B  
Hart  
Ahmed  
Sanaw  
Barcel  
Kane

August 8, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P.  
P.O. Box 8016  
Baltimore, MD 21244-8018

Comment on Medicare Program; Proposed Changes to the Hospital Outpatient  
Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Page 42732 "Drug Coding and Billing"

We concur with your suggestion to eliminate innovator multiple source drugs as represented by C codes and in CY 2006 use HCPCS codes for both brand and generic forms of the drug. We are totally in agreement with this step in decreasing the administrative burden for pharmacy. It is logical to assume that cost will govern the use of pharmaceuticals.

Sincerely,

*Cathy Mezmar*

Cathy Mezmar RN, MSN  
APC Coordinator

6  
AUG - 9 2005

James A. Cucco  
12 Wilber Street  
New Providence, N.J. 07974  
August 5, 2005

Hart Snow  
Barrell Kane

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Re: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am a recent recipient (4/25/02) of prostate cryosurgery and very happy with the results, which I believe was a cost effective procedure. The initial recommendation by my doctors was for seed implants and radiation therapy, starting with hormone treatments. Being a web surfer, I was attempting to find out what side effects I might expect from the initially proposed treatments, and accidentally became aware of cryosurgery while surfing the National Cancer Institute web site. After an extensive investigation of cryosurgery I made an appointment with Dr Aaron E. Katz at the New York Presbyterian Hospital, was examined and found I was a candidate for cryosurgery, and the rest is history. On the day of my scheduled cryosurgery, I walked in the hospital in the morning and walked out (unassisted) that same evening. I had some minor discomfort from swelling and wearing a foley catheter for two weeks, but was able to continue my normal daily routine. Had I opted for the seed implant and radiation, I would have had to undergo daily radiation treatments for five weeks. (40 treatments without seeds) I never cease to be amazed as to why cryo is not more widely offered. Could it be that doctors can make more money doing it the old fashioned way.

I recently became aware that medicare's proposed hospital outpatient payment rates for prostate cryosurgery will not cover what the hospital costs are. As a result, it would seem that fewer hospitals would be offering this procedure. Not being a medical professional, or associated with the medical profession, I was curious as to the 2006 Payment Rates for APC 674, and again on the internet, I took a look at the Federal Register dated 7/25/05 and on page 97 the proposed payment is less than what was paid in April of 2002. What I find puzzling is the fact that I believe cryo treatment is less costly to medicare than some of the other procedures that are available and yet, your proposed payment rates make it less attractive for hospitals to offer it. If the goal is to reduce medicare costs, which I am sure it is, would it not make sense to allow hospitals to cover their costs in order to make it cost effective to offer the cryosurgery procedure.

Very truly yours

James A. Cucco  
James A. Cucco

cc: James F Hart CMS  
Mary Spick, Endocrine

August 3, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Cryo  
Pyint/Kates

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(7)  
Hart Sarrow  
Bazell Kance

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for **APC 674: Cryosurgery of the Prostate**

Dear Dr. McClellan:

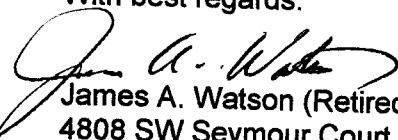
The purpose of my letter is to encourage you to continue and actually increase the benefits paid to doctors and hospitals for this procedure. My interest is that I am a cancer survivor having chosen cryo three years ago over all the other treatment modalities and know that a decision to reduce payments will significantly impact those who desire to choose this option but will not because it is not compensated. I believe it will impact those who choose this as an outpatient treatment with a local anesthetic more than others. Sometimes when a person has COPD or a weak heart, cryo is certainly the least invasive of all the treatment modalities and they would be discriminated against because they couldn't do this based on the lack of cost support. I hope that makes sense. You cannot have a radical prostatectomy with either of those medical issues or if you do it is with significant risk. While I am not a doctor I have spent the necessary time to educate myself. My wife is a nurse and my brother is a nurse practitioner so I have a lot of support in washing these issues through.

I am responding to the notice in the July Federal register that contains the proposed hospital outpatient rates and have been informed that the new proposed rates will not cover what the actual hospital costs are and believe that to be a travesty. If you reduce benefits you can be sure that fewer and fewer hospitals will not be offering this and that is simply how the game is played. Huge mistake on your part.

If you are going to adjust the rates for this procedure please do it in an upward fashion to reflect the actual costs of doing this procedure, which if you will take the time, will discover it to be less than a radical prostatectomy (including laproscopic), than external beam radiation, than Brachy Therapy (seeds), and Proton Therapy. *Why would you reduce the benefits of a procedure that has a 92% success rate with only an overnight or outpatient stay?* That doesn't make sense! After spending one and a half months myself, consulting with three doctors, as well as my wife and my brother I chose to do cryo because of all the benefits. I am three years out, a PSA of 0.1, no issues with incontinence and believe it or not my potency returned after 12 months at age 65. What more can I say? Because this treatment is minimally invasive there is not a long hospital stay, quicker recovery time and fewer residual issues that often accompany other procedures.

I know you have a very difficult task to balance the budget and to be good stewards of our tax money and that is why I am encouraging you to consider what I have said and if anything, cut the benefits to some of the other modalities and not this procedure.

With best regards.

  
James A. Watson (Retired Communications Executive)  
4808 SW Seymour Court  
Portland, Oregon 97211  
503-245-6162

cc: James L. Hart, CMS  
Mary Syiek, Endocare

August 5, 2005

Cryo  
prostate

8

AUG 11 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O.Box 8016

Hart  
Saw  
Bazell  
Kane

RE: CMS-1501-P: Medicare Program; Changes to Hospital Outpatient  
Prospective Payment System and Calendar Year 2006 Payment rates for APC 674:  
Cryosurgery of the Prostate.

Dear Dr. McClellan:

I am writing this letter to express my interest and support in Prostate Cryosurgery Procedures. My main reason for supporting the Prostate Cryosurgery Procedure is the success of my own personal experience with the Cryablation of my prostate cancer, performed October 2, 2001.

This letter then is in response to the July Federal Register that informs me that Outpatient Payment Rates for prostate cryosurgery procedure in 2006 will not cover what the hospital costs are. I would like additional access to prostate cryosurgery with more, not less, hospitals offering this treatment.

The payment rate for APC 674 as proposed, will mean that fewer hospitals will be offering this procedure. (Prostate Cryosurgery)

I would urge Medicare to INCREASE the proposed payment rate for APC 674 to reflect a hospital's real costs to perform the procedure.

My personal reasons for choosing Prostate Cryosurgery over the other treatments offered;

1- Radical Surgery; Rejected due to my age at the time (74).

2- External Beam Radiation; Rejected. I did not want to be exposed to radioactivity and the chances of being burned as has happened to a neighbor.

3- Brachytherapy; Rejected; (The implanting of radioactive seeds) Learned of a couple of occasions of radiation failures.

4- Watchful Waiting; Rejected; Having had bladder cancer, I wanted to rid myself of my prostate cancer as quickly as possible.

Cryosurgery; After reviewing all the pros and cons of cryo, a sure cure in many cases, if the cancer has Not spread outside the prostate. A freeze, thaw, freeze, thaw. All over in less than about two hours. No cutting, no blood, overnight hospital stay, no radiation hazard, quick recovery.

Procedure can be repeated if cancer reoccurs (unlike other options) and has been approved for prostate radiation failures.

Cost effective. I found the overall cost of Cryosurgery was LESS in comparison with Radical, Seed Implant and Radiation.

No hospital stay (Overnight only)

Very truly,

*Andrew Giuffrida*  
Andrew R. Giuffrida

Cc: James L. Hart, CMS  
Mary Syiek, Endocare

DHPPC

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(X-Ref: cis # 488055)

PBT

THE UNIVERSITY OF TEXAS  
**MD ANDERSON**  
**CANCER CENTER**  
PROTON THERAPY CENTER

#1 568617

FUI-1501-P

Debbie Hunter  
Rebecca Kane  
Joan Sano  
Jim Hackett  
Carol Bazell

2005 AUG 19 AM 7:55

August 8, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Room 314 G  
Washington, DC 20201

**Re: Proton Beam Therapy Payment Classification**

Dear Dr. McClellan:

In the Proposed Calendar Year (CY) 2006 Rule (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2006 Payment Rates (CMS-1501-P)), we note the following proposed changes as they relate to proton beam therapy:

1. The proposed rule maintains separate classifications for simple, intermediate and complex proton therapies (CPT-4 codes 77520, 77522, 77523 and 77525, respectively).
2. CMS also proposes to move intermediate and complex proton therapies (CPT 77523 and 77525) from a New Technology APC (1511) into a clinical APC (0667).
3. Payment rates are proposed to be \$764.74 under APC 0664 for simple proton therapies (77520 and 77522) and \$914.92 under APC 0667 for intermediate and complex therapies (77523 and 77525).

We agree with the proposed rule for the following reasons:

1. Maintaining separate APC rates for proton therapies of varied complexity is necessary to differentiate between resource demands of different treatment levels.
2. The proposed rates more accurately reflect the significant capital demands associated with developing, and the high costs of operating, a proton therapy center.

We also note that proton therapy technology is in the early stages of diffusion and as such the number of claims data should be monitored carefully by CMS, as it is expected to be modest for the next two to three years, with an outlook to supporting patient access to proton beam therapy.

We strongly support the classification and payment rates for simple, intermediate and complex proton therapies as proposed in the CMS CY 2006 OPPS rule. We urge CMS to make the proposed rule its final rule for CY 2006. This will ensure that the nation's premier cancer treatment centers have the ability to provide cancer patients with this successful treatment.

Currently, over 46,000 cancer patients have been treated with protons in many institutions around the world, including three institutions currently providing proton beam therapy in the United States. Positive clinical results from these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently numerous facilities are in the planning or construction phases

Proton beam therapy is in an early stage of clinical adoption. The required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment. A typical proton beam therapy center requires approximately \$125 million and more than three years to develop. As a result, the number of sites establishing proton beam therapy centers has not kept pace with the clinical demand for the service. For those sites establishing centers, cost continues to be a major concern, which underscores the importance of maintaining adequate Medicare payment for the technology. It is critical that CMS OPPTS continues to work with the providers of proton therapy to understand and analyze the data for classification and payment, as was clearly seen by the CY 2006 proposed rule, to ensure the economic viability of both existing facilities and those in various stages of development and construction.

Proton therapy is responsible for improving health outcomes, quality of life and our standard for cancer treatment. Appropriate payment rates for proton beam therapy will ensure this leading-edge cancer therapy is available to those we serve.

Thank you for your prompt attention to this critical issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce R. McMaken". The signature is fluid and cursive, with a long horizontal stroke at the end.

Bruce R. McMaken  
Managing Director  
The Proton Therapy Center-Houston, Ltd., LLP

July 30, 2005

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Cryo  
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Hart  
Saxow  
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Kane

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

RE: APC 674 Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing in regards to the upcoming changes to Medicare's schedule of payments for Hospital Outpatient procedures which include cryosurgery for prostate cancer. I am a survivor of prostate cancer, blessed by the advances in cryosurgery techniques.

My wife and I were very proactive in seeking the appropriate treatment for my situation. My diagnosis came while we were between insurance plans so it was considered pre-existing and, of course, that meant we would be paying the entire medical bill. We reasoned that since cryosurgery was being used for salvage (where other treatments had failed and cancer returned), and since it was the least invasive form of surgical treatment allowing a much shorter recovery time, and the overall cost of the procedure was quite a bit less than other forms of treatment, it made good sense to choose cryosurgery. I refer to it as 'my treatment of choice.'

I need to add that I was a young 59, not yet a Medicare recipient, when diagnosed and was very physically active. I've often noted that I didn't have time for such a condition. It was a good thing to have cryosurgery available because it allowed me to return to a normal lifestyle much quicker than many men I've heard from.

And I speak with a good number of men facing their own choices for prostate cancer. I am a part of a peer support system which offers encouragement to those men seeking information and direction.

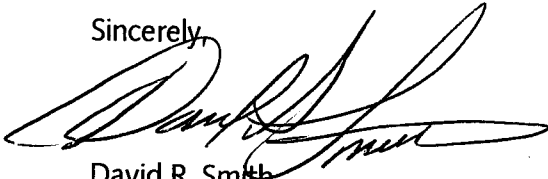
While my own experience included an overnight stay, the surgical process can be effectively performed in an outpatient setting. It's generally less costly and, as such, the reasoning behind Medicare's intended plans to reduce or eliminate paying for cryosurgeries performed in outpatient facilities is baffling to me.

I would encourage Medicare to revisit this issue and restructure their payments to reflect a facility's actual cost, whether a hospital outpatient center or a stand-alone outpatient facility. The procedure, itself, would provide a cost savings to Medicare if more men and doctors elected cryosurgery over the more complex, expensive, and sometimes troublesome treatments.

The direction Medicare appears to be taking will, no doubt, reduce the number of cryosurgeries performed. That serves the best interests of no one. It will only cause a reduction in the availability to the many men who would greatly benefit from such a successful procedure.

More hospitals need to make this life-saving treatment a part of their ongoing procedures. More doctors need to be trained as certified cryosurgeons. More men need to be informed as to this excellent option so they can make informed choices for treatment. And I firmly believe Medicare needs to play a viable and supportive role in expanding the use of cryosurgery rather than taking action which will only stifle it and, perhaps, damage its acceptance within the medical community.

Sincerely,

A handwritten signature in black ink, appearing to read 'David R. Smith', with a stylized, flowing script.

David R. Smith  
CEO & Managing Partner  
Financial Education Services, LLC  
P.O. Box 3777  
Turlock, CA 95381-3777

Cc. James I. Hart, CMS  
Mary Syiek, Endocare, Inc.

August 1, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator, Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

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RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing this letter as a Medicare recipient and a prostate cancer survivor due to Cryotherapy and my interest in seeing others are afforded the same life saving and nerve-sparing procedure.

My ordeal began in September 2003 with a PSA level of 4.6 and a biopsy in December of that same year. Mistakenly I thought I was out of the woods when no cancer was detected. However in October, 2004 my PSA level was at 6.9 and another biopsy was ordered. This time 3 of the 12 samples taken showed cancer cells. I was devastated, unless one has heard a diagnosis of cancer there are no words to express the fear and dread it conveys. I was certain if I lived, my life would be forever altered and I would no longer be able to contain my bladder or have sexual relations.

God led me to a skilled urologist, Dr. Steven Hulecki, who performed Cryotherapy on January 28, 2005. Today my PSA level is 2.8 and I am able to enjoy all aspects of a normal, healthy life. I know had I not had this procedure things would be very different for me.

A notice in the July Federal Register mentioned that the proposed Medicare hospital outpatient payment rates for prostate Cryotherapy in 2006 would not cover the hospital costs. This is distressing to me as I think fewer patients will have access to this procedure if Medicare lowers the rate it pays hospitals. The hospitals will no longer offer this option due to the inadequate payment rate Medicare is proposing. Therefore the benefits of Cryotherapy, which is a minimally invasive procedure and produces fewer side effects, would be lost. Ultimately Medicare would pay out more for subsequent health care, which are caused by the other prostate cancer removal options.

In closing, I urge Medicare to adjust the proposed payment rate for APC 674 upward—to reflect the actual costs incurred by the hospital in performing this procedure. In my opinion the benefits to Cryotherapy are numerous. They include a quicker recovery time, less chances of bladder control problems and a possible return of sexual functions, while still curing the prostate cancer.

Sincerely,

*Sanford K. McBee*

Sanford K. McBee

Cc: James L. Hart, CMS  
Mary Syiek, Endocare

new 12  
Cryp

Dana Barker  
Rebecca Ken  
Joan Sanson  
Jim Hart  
Carol Baze

**Subject:** Cryotherapy

**From:** Colin Campbell <colinc@bmts.com>

**Date:** Mon, 08 Aug 2005 16:33:37 -0400

**To:** <http://www.cms.hhs.gov/regulations/ecomments@bmts.com>, [james.hart@ms.hhs.gov](mailto:james.hart@ms.hhs.gov)

**BCC:** [msylek@endocare.com](mailto:msylek@endocare.com)

Gentlemen:

Re;CMS-1501-P Medicare Program.Payment rates for APC674: Cryosurgery of the Prostate>

Dear Dr Mc Clellan. MD. PhD

I am writing from Canada where we are well behind the USA in the treatment options we are given to treat prostate cancer..

Any move by Medicare to reduce the payment for those men who can benefit from Cryotherapy will greatly reduce the chances of us getting it approved as a treatment for this disease which affects and kills so many men.

Those men who have greatly benefitted from primary Cryosurgery by going to the USA at great personal cost will testify to the efficacy of Cryosurgery.The work of Dr Duke Bahn et al and also that of Professor Bryan Donnelly resulted in approval of the procedure in one of ten Provinces and two territories, but the Medical Profession in Canada still consider this as experimental,if you can believe that!

The fact that Cryosurgery is the only treatment which can be repeated and that it is essentially an Outpatient procedure by itself should result in cost saving to Medicare, since follow up treatment of failed RP results in significant cost increases!!

I chose Cryosurgery for the reasons given above and have recommended the procedure to men I have been in contact with as Chairman of an USTOO Support Group and all of whom have had excellent outcomes.

Yours sincerely

Colin Campbell ; MSAE; MCAI; CET. OCE

Cryo

new  
13

William R. Molzon  
6850 Deerhill Drive  
Clarkston, MI 48346  
August 8, 2005

Mark B. McClellan M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Dann Buzley AUG 17 2005

Rebecca Kane  
Joan Samson  
Jim Hart  
Carol Buzley

RE: CMS-1501-P: Medicare Program - changes to hospital outpatient payment system and 2006 payment rates for APC 674: Cryosurgery of the Prostate

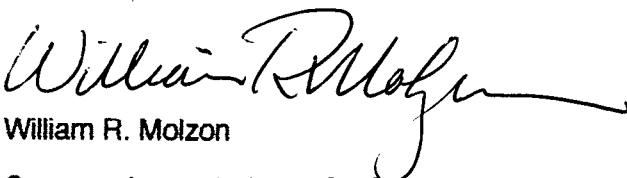
Dear Dr. McClellan:

This letter is in response to a notice that I understand was in the July Federal register regarding the proposed hospital outpatient payment rates for Prostate Cryosurgery in 2006, which I understand does not cover what the actual hospital costs are for the procedure.

I had Cryosurgery for my Prostate Cancer in 1994, have a low, stable PSA with no signs of recurrence or any complications from the procedure, but would definitely want Cryo as a treatment option should the cancer ever recur. I consider it the best option for getting rid of the cancer with minimal side effects and complications, and would hope that it would be readily available as an option for others confronted with the diagnosis of prostate cancer. Cryo is more cost effective than surgery, and from the statistics I have seen, has a success rate at least as good or better than surgery in curing the disease, along with lower morbidity and less complications, so would hope to see more hospitals offer it as a treatment option rather than fewer, which would likely be the result if the funding is decreased so that the cost to the patient is more than for other treatment options. When I had Cryo in 1994, even though the procedure was considered experimental at that time, it only required an overnight stay in the hospital compared to several days for surgery at the time, and the recovery period was much less - days instead of weeks (with less risk of complications), so from my own experience, would definitely choose Cryo again.

I therefore urge you to adjust the proposed payment rate so that it will cover the actual hospital cost for performing Cryosurgery procedures so that future patients faced with the decision of how to best treat their cancer can choose their treatment option based on the merits of the procedure rather than having to make their decision based on financial coverage considerations.

Yours truly,



William R. Molzon

Cc: James L. Hart, CMS  
Mary Syiek, Endocare

new  
14

August 14, 2005

AUG 17 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Ceyo

Dana Burley  
Rebecca Kure  
Joan Sanow  
Sim Hark  
Carol Bazell

*RE: CMS-1501-P: Medicare Program' Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate*

Dear Mr. McClellan:

*I am writing to you in the hope that you will experience the emotion with which I am expressing myself.*

*It has come to my attention that the funding for cryo ablation patients through Medicare is in jeopardy. As a recent beneficiary of the cryocare procedure (10-20-2004) I would like you to hear my story.*

*At my present age of 79, I have had a 12 year history of Prostate Cancer. My PSA level in mid 1993 was 22.8. My oncologist advised me after confirming the cancer diagnosis via biopsy exam, that my choices of treatment were "seed implant", radical prostatectomy, or radiation. The thought of a prostatectomy sent chills through me. An exam by another doctor determined that I was not a candidate for "seed implant". I then underwent a series of 37 radiation treatments, which reduced the PSA for about 4 years. At that time my oncologist told me that the treatment of choice was a hormone injection of (Leuprolide acetate suspension) "Lupron" every 90 days. Needless to say the expense to Medicare was considerable for both the radiation and the Lupron injections over the course of treatment. I asked the doctor how*

long these expensive injections would be necessary and was told I would need them as long as I live.

It was a TV ad that brought the Cryocare procedure for prostate patients to my attention. It was stressed that those who had failed radiation and hormone treatments could benefit.

The patient advocate at Cryo Care put me in touch with an experienced and respected urologist. He examined me very extensively. It was determined that the radiation and hormone treatment had failed and my cancer was again raging. After a complete battery of tests it was determined that I would be a good candidate for the Cryo-procedure, which was scheduled and completed 10-20-2004. Since then I have had three PSA reports and all three came in at less than 0.1 or barely measurable. I am elated with the success and have experienced no pain. The discomfort following surgery was minimal and I now feel great.

In summary, let me point out that most men will experience prostate difficulty or even cancer. If it can be found early, the number of lives saved and the enormous saving of expense to Medicare and the patient must be very significant.

As a personal note, if you find your PSA to be elevated or anyone you know has the symptoms of prostate trouble, please investigate the possibility of preserving your life and the lives of the ones you care about with cryocare. The side effects are minimal and the benefits are beyond measure.

Thank you for reading this far. Feel free to contact me regarding this letter at any time.

Respectfully,



Edward A. Schreiner  
342 Sandpiper Lane  
Marysville, MI 48040  
810-364-5625

cc: James L. Hart, CMS  
Mary Syick, Endocare

NT

APC Weights  
Impact

Debbie Hurst  
Anita Heygster  
Rebecca Kane  
Joan Sanow  
Carol Bazell

new  
15

same as P-24

AUG 19 2005



ORTEC INTERNATIONAL, INC.  
WWW.ORTECINTERNATIONAL.COM

C. PAPASTEPHANOU, PhD  
PRESIDENT & CHIEF OPERATIONS OFFICER

August 18, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Management  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule", July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan;

Ortec International is a development stage biotechnology company located in New York. An investment of over \$150 million has been made to make our product OrCel® a reality. OrCel® is a skin substitute composed of dermal and epidermal cells coated on a layer of collagen sponge. This product was designed for the treatment of hard to heal wounds such as venous leg ulcers and diabetic foot ulcers.

I would like to request your assistance in resolving an issue of critical importance to Ortec. In the Hospital Outpatient Prospective Payment System Proposed Rule, CMS has set the current APC reimbursement rate for OrCel® (APC 9200) at \$159.59 per unit. This represents an 86% reduction from the CY 2005 rate of \$991.85. Furthermore, the manufacturing cost for OrCel® has increased rather than decreased and currently costs Ortec approximately \$1000 to manufacture.

We believe this inaccurate rate results from an error in the rate setting process. In the Proposed Rule, CMS identified its rate setting methodology for CY 2006 as resulting from data obtained from three sources: 1) the GAO hospital outpatient drug acquisition cost survey; 2) average sales price (ASP) data from the fourth quarter of 2004; and, 3) the mean and median costs derived from the CY 2004 hospital claims data.

Although OrCel® has been available in limited quantities as part of approved clinical trials; Ortec ceased marketing OrCel® commercially in 2002 to develop a longer shelf life product and focus on clinical trials for the use of OrCel® in venous leg ulcers. Therefore, data should not have appeared in any of the three databases. If cost data did appear, it would have been a result of erroneous billing on the part of hospitals or other providers.

We would like to meet with the appropriate individuals in your office to clear any misunderstanding and would be very grateful if your office could call us to arrange a meeting and help us reach an equitable reimbursement rate for our product. I can be reached at 646.522.1927 or by Email at [costa.papastephanou@ortecinternational.com](mailto:costa.papastephanou@ortecinternational.com).

Sincerely yours,

cc: H. Kuhn  
T. Gustafson  
E. Richter

new 16

Cryo

---

Augusta Urology Associates, L.L.C.

James J. Carswell, III, M.D.  
Mark L. Cain, M.D.

Charles H. Coleman, Jr., M.D.  
Richard B. Sasnett, Jr., M.D.  
Henry N. Goodwin, Jr., M.D.

Michael F. Green, M.D.  
J. Douglas Quarles, Jr., M.D.

CRYO Dana Borking  
Rebecca Kane  
Joan Sanow  
Jim Hart  
Carol Bazell

August 16, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
ATTN: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

RE: CMS-1501-P: for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan,

The reason I am writing this letter is for your consideration concerning reimbursement for cryosurgery of the prostate. I have been doing cryo oblations of the prostate for prostate cancer for almost a year and a half now, and have found it to be a tremendous asset to the treatment of prostate cancer, especially in those individuals who are over the age of 70, who have localized disease with the potential for cure.

I have essentially been using this in lieu of radiation therapy or both external beam and interstitial therapy. Also, it is a wonderful mode of therapy for patients that failed radiation therapy, because it is the only thing available for local treatment of those failed radiation patients.

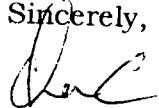
It is my understanding that the proposed reimbursement rate is far under the proposed cost of the procedure, both in the inpatient and outpatient setting. If this practice is allowed to be implemented, then certainly it would probably stop the use of cryotherapy in the treatment of prostate cancer, which I think would be a tremendous detriment to patient care. In the long run, I think this would create a tremendous cost overrun, since most of these patients would be shifted to the radiation therapy mode of treatment, which I'm sure, costs much more than cryotherapy and is wrought with many more complications.

I started doing cryosurgery because of the complications associated with radiation therapy, and the short term treatment that's involved, rather than treatment that goes on for weeks. Cryosurgery provides much more convenient care for the patients as compared to external beam therapy, which requires anywhere up to eight weeks. For some of my rural patients who have to travel great distances for treatment, cryotherapy is much more advantageous to them, rather than radiation therapy.

Economically, if Medicare refuses to pay at a rate that is commensurate with the cost, then they are effectively taking this out of the treatment for prostate cancer. I understand clearly the cost problems that you are dealing with in terms of trying to save on Medicare reimbursement. However, when considering this, I don't understand why you would pay less

for treatment for cryo than you would for a Brachytherapy treatment for prostate cancer, both seemingly being equally effective, and one carrying a lot lower morbidity rate.  
I certainly hope that you would reconsider your plans in this regard.

Sincerely,

A handwritten signature in dark ink, appearing to be 'ChC' with a flourish, representing Charles H. Coleman, Jr.

Charles H. Coleman, Jr., M.D.

CHC/ctf

c: James L. Hart, CMS

CRYO Dana Buzley  
Rebecca Kane

new  
17

DRAFT COMMENT LETTER  
PHYSICIAN LETTER EXAMPLE

[insert date], 2005

Joan Sanow  
Jim Hare  
Carol Bazell

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

- In a sentence or two, let Medicare know the purpose of the letter your expertise in prostate cryosurgery procedures and that you are responding to a notice in the July Federal Register that contained the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006.
- For example, relay that you are a practicing cryosurgeon and how many procedures you perform annually; or, if you are a physician interested in performing prostate cryosurgery procedures, mention that you are considering offering this service to your patients.

Let Medicare know that the proposed payment rate for APC 674, Prostate Cryoablation (\$5,659.13) that Medicare has proposed for 2006 would not cover the costs that your hospital incurs to perform this procedure.

- Let Medicare know that you understand that it costs hospitals over \$9,000 to perform this procedure—but the proposed payment rate for 2006 is only \$5,659.
- Let Medicare know when you starting performing cryosurgery, why you chose to learn to perform the procedure, and its benefits compared to other prostate cancer treatment alternatives.
- You might compare prostate cryosurgery to RP for primary and salvage RP to salvage cryosurgery. You might discuss morbidity. You might mention time of recovery and return to work/daily living. You might give a case example of why cryosurgery was effective with a patient.
- You should mention that you do not want to be forced to deny patients access—to be steered in your choice of therapy—by the payment rates Medicare sets. If the rates are not adequate, hospitals will not offer the procedure—and medical practice will be affected negatively. Patients will pay the price if Medicare payment rates that are set incorrectly.

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You should provide any examples where reimbursement concerns required you to you admit a patient to different hospital.

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... will improve clinical outcomes at less cost to the government

*Mary Syiek, Endocare*

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Original is bad quality

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CRYS

Dana Burkley  
Rebecca Kane  
Joan Sano  
Jim Hark  
Carol Bazell

August 18, 2005

Mark B McClellan, M. D., Ph. D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient  
Prospective  
Payment System and Calendar Year 2006 Payment Rates for APC674: Cryosurgery  
of the Prostate

Dear Dr. McClellan:

I am writing you to express my concern for the proposed reduction in payment rates for Cryosurgery procedures.

March 22, 2004 I had the Cryosurgery procedure performed on me in Santa Barbara, CA by Urologist, Dr. David Laub. The procedure was successful and I was back working in two days and my PSA level has been below 0.2 ever since.

However, if the cancer ever returns I can have the Cryosurgery again to remove it. As you know I could not have a repeat of any of the other procedures, ie, radical surgery, radiation, seed therapy if I had had them done originally .

I see in the July Federal Register that the proposed prostate Cryosurgery reimbursement rates will not cover the actual hospital costs. This will result in fewer hospitals and Doctors offering this procedure and will be an adverse reaction to a problem that most men have. The payment rates should be increased, not decreased for APC674.

In January 2004 when I had tests that revealed a PSA level of 4.7 and a biopsy that confirmed prostate cancer, I went to three urologists that specialized in radical prostatectomy, radiation, and seed therapy. All of those procedures had too many adverse side effects. Of course the Doctors recommended the procedure that they were trained in and were competent at performing.

I found Dr. David Laub in Santa Barbara and he did all the above procedures plus he did the freezing technique called Cryosurgery. Dr Laub said that I was a better prospect for the Cryosurgery and that is what he recommended and I agreed with him. I found out later he could have done any of the other procedures and made more money but he chose the best procedure for me.

I hope you can help raise the payment rates for Cryosurgery so that I and other patients will have a better choice for prostate cancer treatment.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard Cook".

Richard Cook

P. O. Box 543

Broken Bow, OK 74728

Cc: James L Hart, CMS  
Mary Syiek, Endocare  
Dr. David Laub

APC-Gene Dana Burley New 19  
Cryo

Dana Burley  
Rebecca Kane  
AUG 17 2005  
Joan Sanow  
Jim Hark  
Carol Buzell

Mark McClellan, M.D., Ph.D.

This letter is to urge Medicare  
to adjust payment rates for  
APC 674 upward to reflect  
Actual Cost

I support prostate cryosurgery  
procedures, partially and totally.

For me personally, I only  
spent 28 hours in the hospital,  
got out and drove 250 miles  
back home. After only a  
few days I resumed normal  
activities. This choice of  
treatment will only be  
greater in the future as  
procedure and knowledge is  
made available. This can  
only happen with more hospitals  
and doctors being involved  
in this type of treatment.

The decisions you make  
should not be based on dollars  
but on treating patients with  
this terrible illness, please  
give them a choice

Respectfully

Paul Sherman  
P.O. Box 3 - Christmas Valley Or. 97641

8/15/2005

new 20 Crys Dana Buckley  
Rebecca Kane  
Joan Sano  
Jim Hark  
CAROL Buzell

Mark J. McClellan, M.D., Ph.D.

Administrator

Centers for Medicare and Medicaid Services

Dept of Health & Human Services

ATTENTION: CMS-1501-P

P.O. Box 8016

Baltimore, MD 21244-8018

RE: CMS-1501-P Medicare Program: Changes to the  
Hospital Outpatient Prospective Payment System and  
CY 2006 Payment Rates for APC 674: Cryosurgery of the  
Prostate.

Dear Dr. McClellan,

I've learned through the July Federal Register  
that the proposed 2006 rates for outpatient prostate  
cryosurgery will not cover hospital costs. I had  
prostate cancer cryosurgery in June of 2004 and  
recovered with PSA results of zero since  
that time. The procedure was performed on an out-  
patient basis. Much like the wonderful improvement  
in gall & bladder surgery, prostate cryosurgery  
is much less invasive than previous surgeries.  
(over)

Original

new

21

Cryo

Dana Burley

Rebecca came

AUG 17 2005

Aug 15 2005

Joan Sano

Jim Hawk

Carol Bazzell

TO CONCERNED

My NAME IS ROBERT M. ZAMBO SR, AT THE AGE  
OF 78, MY P.S.A. WAS HIGH. I WAS SENT TO DR.  
HAWATMEN, HE RECOMMENDED THAT I HAVE  
CRYOSURGERY OF THE PROSTATE. ON OCT 7, 2004  
I HAD CRYOSURGERY AT ST. ANTHONY'S THIS  
WAS VERY SUCCESSFUL, I FEEL THIS OPERATION  
SHOULD BE CONTINUED, AS IT WAS GOOD FOR  
ME AND IT WOULD BE FOR OTHERS, THE  
RECOVERY WAS SHORT IN TIME

SINCERELY

Robert M. Zamba SR

10057 STONELL DR.

ST LOUIS MO.

63123

New 22 Cryo Dana Bueley  
Rebecca Kane  
Joan Sanow

New 22 Cryo Dana Bueley  
Rebecca Kane  
Joan Sanow  
Jim Hare +  
Carol Buzell ed.

Greetings!

The purpose for this letter is in  
response to a notice in July's Fed.  
register.

I was to have 1 hour of daily  
radiation for "6" weeks because the  
doctor thought it to risk for my  
age "76".

I was in and out of the hospital  
the same day, with no adverse  
effects other than normal recuperation.

I researched the procedure and  
talked to several who have had  
traditional and Cryo. Cryo wins  
hands down.

I hope all are afforded the  
opportunity to choose Cryo surgery.

Thank you.

Conrad E. Rubens

Cryo Dana Burkley

New 23

Dana Burkley  
Rebecca Kane  
Joan Sanow  
AUG 18 2005  
Jim Harb  
Carol Bazell

08/15/2005

TO WHOM IT MAY CONCERN,

MY NAME IS GEORGE WARDINGLEY I HAVE HAD PROSTATE CRYO SURGERY AT RUSH UNIVERSITY HOSPITAL PERFORMED BY DR. MCKIEL. BASED ON 5 AND 7 YEAR PUBLISHED STUDIES OF PSA OUTCOMES, CRYOCARE (TCAP) AND ALL FORMS OF RADIATION PROVIDE SIMILAR CANCER CONTROL FOR LOW RISK PATIENTS. FOR MODERATE AND HIGH RISK DISEASE IT WORKS CRYOCARE TCAP MAY PROVIDE SUPERIOR CANCER CONTROL OVER ALL FORMS OF RADIATION. CLINICAL STUDIES CONSISTENTLY SHOW THAT THE NEGATIVE BIOPSY RATES FOLLOWING CRYOCARE TCAP ARE LOWER THAN THOSE FOR ALL FORMS OF RADIATION. JUST TO LET YOU KNOW EXTERNAL BEAM OR 3D CONFORMAL RADIATION THERAPY AND INTERSTITIAL RADIATION CAN KILL MEN OVER 60 YEARS OF AGE. RECENT STUDIES HAVE SHOWN THAT FOR SOME MEN CRYOCARE TCAP MAY BE PERFORMED WITH MINIMAL DAMAGE TO THE NERVES NECESSARY FOR SEXUAL FUNCTION. WITH CRYOCARE I KNOW I WILL LIVE LONGER. WITH THE MEDICARE REIMBURSEMENT APPROVAL DOCTORS CAN AND WILL OFFER CRYOCARE TCAP AS A FIRST LINE TREATMENT TO ALL MEN SO WE CAN LIVE LONGER. RADIATION KILLS MEN WHO HAVE PROSTATE CANCER. PLEASE HELP US LIVE.

SINCERELY,  
GEORGE WARDINGLEY

August 8, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am writing out of concern that future prostate cancer patients may not be able to receive Medicare reimbursement for outpatient cryosurgery.

My father is a prostate cancer survivor who chose the cryosurgery treatment. It was not invasive surgery. My father had no side effects and was back to his routine in days. He is celebrating his fifth year being cancer free with an excellent outlook.

This letter is in response to a notice in the July Federal Register that contained the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006. I have been informed that the new proposed rate will not cover what the hospitals costs are. Therefore, newly diagnosed prostate cancer patients may not be able to afford the cryosurgery treatment or worse, may not be informed of the option by their doctor due Medicare not covering the cost of the treatment.

The inadequate payment rate for 2006 will mean that fewer patients will be able to take advantage of this effective treatment. The elderly citizens of this nation need to continue to have cryosurgery treatment as an option for prostate cancer available through Medicare. Too many of them are facing increasing costs on a limited income. How can you ask them to face increased medical costs when dealing with cancer treatments? I urge Medicare to adjust the proposed payment rate for APC 674 upward to reflect a hospital's actual cost to perform the procedure.

Sincerely,

*Debbie C. Sasso*

Debbie C. Sasso  
5 Lottie Drive  
Grafton, MA 01519

2 OF 24

24-0

(2)

AUG 11 2005

*Cry  
Ryot/rates*

*Hart  
Bazeel  
Sasso  
Kane*

Everette Bowie  
6520 Masters Drive  
Olive Branch, Mississippi 38654-8238

August 12, 2005

Mark B. McClellan, MD, PhD  
Administrator Centers for Medicare and Medicaid Services  
Department of Health & Human Services  
Attention: CMS-1501-P  
P. O. Box 8016  
Baltimore, Maryland 21244-8018

Re: CMS-1502-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am responding to the notice in the July 2005 Federal Register. Therefore, I wanted to let you know of my interest in Cryosurgery of the Prostate for eradication of Prostate cancer. In April 2004 I learned I had Prostate Cancer and was called in to discuss options with my Urologist. He gave me ten options, but took radical surgery off the table due to my age at the time, 78 years. I took seed implants off my self, leaving eight options to choose among. The three top options he presented were watchful waiting, Lupron injections, and Cryosurgery. He gave my wife and me time to consider all the options, including the remaining five. After considerable discussion with the family, and research on our options, we chose, and on July 27, 2004 I had Cryoblation.

My reasoning went something like this: With watchful waiting I was uncomfortable, since I did not like the idea of cancer cells roaming my pelvis looking for a new home. That left Cryo and Lupron injections. With Lupron, I would need an injection every four months for years to come, at \$3,400.00 each, or \$10,200.00 per year, year in and year out. Hot flashes and other uncomfortable side effects were considered; along with the possibility some kind of surgery some day could still become a reality. We then evaluated Cryo, and after a family conference we elected that option.

Let us look at the expense of Cryo compared to other options. Each one, including direct beam, radiation, and radical surgery would require as much if not more in total expense to Medicare than Cryo. Let us estimate the cost of Cryo at \$15,000.00 and realize this is a one time expense, not to ever be repeated, and only one to two days in the hospital. Then consider just one other option, Lupron. At \$10,200.00 per year we would, in one and one-half years spend as much as Cryo, and would have to continue for years.

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AUG 16

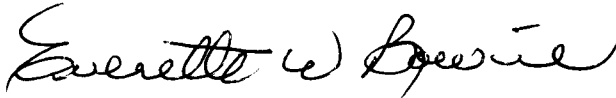
Myint Kates  
Hart  
Sawyer  
Bazell  
Kane

My prostate was completely obliterated by the Cryoblation, and three successive PSA tests have all resulted in less than 0.1 non-detectable each time, suggesting a complete cure. My wife and I continue to believe this is an option that should be available in more hospitals, and more doctors should learn to use it, since we believe it is the surest method to success. I have counseled several new patients in the advantages of Cryo, and can tell you without equivocation that I think it is the best and least expensive treatment of active Prostate Cancer.

For the reasons stated above, and others that would make this communication too long, I urge the restoration of reimbursement rates for this procedure. I could not be happier for my choice.

Thank you for your kind consideration of my request.

Respectfully,

A handwritten signature in cursive script, reading "Everett W. Bowie".

Everette W. Bowie  
6520 Masters Drive  
Olive Branch, MS 38654-8238  
662-895-9231 Home  
901-490-9994 Cell

**Kenneth G. Varley, M.D., F.R.C.P.C.**

*Diplomate, American Board of Anesthesiology  
Subspecialty Certification in Pain Management  
Diplomate, American Board of Pain Medicine*

**Andrew J. Rózsa, Ph.D., A.A.P.M.**

*Diplomate, American Academy of Pain Management  
Medical Psychology*



26 Jan Steading, M.S.N., C.R.N.P.

Board Certified, American Nurses Association

Repeat Devices/Device Cat

August 11, 2005

AUG 16 2005

HEVI

Centers for Medicare/Medicaid Services, DHHS  
Attention: CMS-1501-P  
PO Box 8016  
Baltimore, MD 21244-8018

Hart  
Sarnow  
Bazell  
Kane

To Whom It May Concern:

I am writing regarding the CMS proposal to modify hospital outpatient pass through criteria. This refers to file code CMS-1501-P, issue identifier IV.D.2.c criteria for establishing new pass through device categories, existing device category criteria.

CMS has already approved direct pass through for hospital inpatient services, however I am writing to encourage CMS to extend this pass through to hospital outpatient departments and ambulatory surgical centers. Spinal cord stimulators can be implanted through a low risk minimally invasive procedure that can easily be done in a hospital outpatient department or ambulatory surgical center. Rechargeable neurostimulators have been a tremendous advance to the field of neuromodulation in the treatment of chronic intractable pain. This will, over time, greatly reduce the cost of care as the replacement of impulse generators every 3-4 years will no longer be necessary. In order for this to be properly implemented, a new category of implantable devices specifically for rechargeable impulse generators needs to be applied to implement the pass through policy. The rechargeable devices are significantly different than preceding devices and represent a substantial clinical improvement, as well as cost savings for a large number of patients who are suffering from chronic intractable pain.

I hope you take these comments under consideration when you are establishing new policies regarding implantation devices. I also hope that CMS will give similar due consideration to applying equal access to care in a hospital outpatient, ambulatory surgical center and physician office procedure suites for interventional pain management procedures. This policy of no differentiation in access or payment to care received in hospital outpatient departments, ambulatory surgical centers, and in-office procedure suites has previously been articulated and recommended by Med-Pac in a report tabled in 2001. We are still waiting for the implementation of this policy and feel it is ultimately in the best interest the patients we serve.

With best regards,

Kenneth G. Varley, M.D., F.R.C.P.C.

Compassionate ♦ Multidisciplinary ♦ Diagnosis ♦ Treatment

7500 Hugh Daniel Drive, Suite 360 ♦ Birmingham, Alabama 35242-7144

(205)995-9967 ♦ (205)995-0635 FAX ♦ (888)436-4560 TOLL FREE

[www.southernpain.com](http://www.southernpain.com)

John D Cochrane III  
1530 Edinborough Rd.  
Ann Arbor, MI 48104  
734-971-7399  
jdcochrane@comcast.net

27

AUG 16 2005

Cryo  
Hart/Kates

Hart  
Sawyer  
Barrell  
Kane

8/12/05

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

RE: CMS1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for **APC 674: Cryosurgery of the Prostate**

Dear Dr. McClellan

I chose cryo surgery when I found I had prostate cancer in July 1995. My analytical engineering training from Purdue told me it could provide me the best cure for my very aggressive Gleason 9 (5+4) score. I even paid for the procedure myself because Medicare considered it still "experimental and investigational." I wouldn't touch a radical prostatectomy or any of the various radiation procedures because of their unimpressive cure figures and the many downside problems like impotence, incontinence and bowel problems, etc.

Cryo is minimally invasive and is usually an overnight stay. That's big bucks saved for hospitals.

Today, 9 years 7 months later I'm pleased with a psa of 0.1. I'm completely dry and "Willie" doesn't work - but at 79, who cares! Cryo's, "2nd coming" began to accelerate around 1994 when better freezing and monitoring equipment became available. (Early history results were very poor.) The current 10 year survival data are truly outstanding. Cryo handles high Gleasons like mine when no one else will touch it. They are also doing nerve sparing procedures now. Cryo is the procedure of choice for failed radiation procedures, of which there are unfortunately way too many.

And at this current date I see hoards of patients dropping the radical procedure like rats leaving a sinking ship because of the downside problems. Older seeds implant patients are beginning to experience significant incontinence problems as has been predicted.

#### **July Federal Register**

And then I learn from the July Federal Register you plan to lower the outpatient reimbursement rates for prostate cryosurgery in 2006 to the extent that hospitals won't even be able to cover their current operating costs. That is absolutely absurd. If hospitals can't cover their costs, you know their doctors will never recommend the procedure. They should at least be allowed to break even!

Your proposed action will undoubtedly be the coldest, wettest blanket you could possibly use to smother this continuing, dramatic Cryo revolution of the past 4-5 years.

I paid for my Cryo out of my pocket because Medicare wouldn't. I personally fought Medicare for 18 months following my Cryo to get them to reimburse me **AND I WON.**

Thousands and thousands of men and their families are on this Cryo bandwagon. And it isn't just for prostate cancer. It is also being aggressively used for liver and kidney cancers and others because the results are superior to the surgeon's scalpel. Your proposed action will stop the prostate portion of this revolution in its tracks. We need more hospitals offering Cryo, not fewer.

Please, Dr. McClellan, when the time comes to vote this issue, don't knock down the hopes of all those men who need and are asking for this outstanding protocol. I know Medicare's costs are skyrocketing, but you must do the right thing and raise the hospital's compensation level so they can at least break even. Cryo will save you bushels of money in the long run and you need all the help you can get.

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Dr. McClellan, if you have gotten this far in my plea for justice, indulge me just a bit more and allow me to expand upon my previous encounter with HCFA regarding my cryosurgery procedure. I believe you will find it interesting and hopefully persuasive. I'm John D. Cochrane, III and they call me Jack. 289-24-6976. You can look it up in my Medicare records. I live in Ann Arbor, MI. 734-971-7399.

I mentioned earlier Medicare wouldn't pay. For 18 months following my Cryo procedure, I followed protocol and wrote a series of letters to HCFA in preparation for eventually going before an Administrative Law Judge to plead my case. Before I reached that final stage, I received a preemptive letter on Aug. 28, 1997 from Admin. Law Judge James N. Gramenos in which he told Medicare to reimburse me for my out-of-pocket expenses.

The following is an excerpt from page 2 in the DISCUSSION portion of Judge Gramenos' findings:

" Mr. Cochrane's various communications with the Medicare intermediary are contained in the filed. They demonstrate an advanced understanding of cryosurgery, a sense of the absurdity of Medicare's continuing denial of coverage for the procedure and a sense of humor. Mr. Cochrane has offered several reasons why cryosurgery is no longer investigational but can be the preferred method of treatment in terms of success and economy."

I don't need to get into a hassle with Medicare again. I'm too old! Do what is just and correct. Please raise the hospital's baseline figure so more hospitals will have the incentive to offer Cryo.

Sincerely



Jack Cochrane

- with a psa of 0.1 after almost 10 years

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AUG 16 2005

DANIEL F. WALCOTT

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Fort Wayne, IN 46814

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Cnjo  
Pyntt/Kates

Hart  
Sanow  
Barell  
Kane

August 11, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Center for Medicare & Medical Services  
Dept. of Health & Human Services  
Attn: CMS-1501-P  
P. O. Box 8016  
Baltimore, MD 21244-8018

RE: APC 674: Cryosurgery of the Prostate -- Proposed Year 2006 Payment Rates

Dear Dr. McClellan


I have recently learned, with considerable alarm, of the planned Medicare drop in reimbursements to hospitals for cryosurgery. Having recently undergone this procedure, I can attest to it's efficacy and cost effectiveness. Additionally, it offers several options not available to those choosing either brachy therapy, other radiation-type procedures, or surgical prostate removal.

For example, should cryosurgery fail, other options are still available. This is not the case with brachy therapy. Patients, having undergone unsuccessful brachy therapy may not ordinarily be able to subsequently opt for surgical prostate removal. In addition, due to the brittle nature of most prostate glands subsequent to brachy therapy, cryosurgery, while still an option, is much more difficult and expensive. Also, as I am certain you are aware, incontinence is most often an unfortunate by-product of surgical prostate removal.

My personal experience with cryosurgery has been wonderfully successful. I spent one over-night in the hospital with discharge early the following morning. The surgical procedure was undertaken on March 17 and, as of this date, I am completely cancer free.

For the benefit of future patients as well as Medicare, I urge your immediate reconsideration of this planned reduction in reimbursement rates. If such is not the case, hospitals will not be financially able to accept assignment of Medicare, physicians will not be inclined to recommend cryosurgery, and patients will be the loser.

Thank you for your consideration of this urgent special request.

Sincerely,  
  
Daniel F. Walcott

Cc: James L. Hart, Deputy Director

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*29*  
*29*

AUG 16 2006

**Richard D. Seaman**

Engineer & Business Management Consultant

10462 Boca Canyon Drive

Santa Ana, CA 92705

Mark B McClellan, MD

Administrator

Ctr. For Medicare & Medicaid Services

Dept of Health & Human Services

Attn: CMS-1501-P

PO. Box 8016

Baltimore, MD 21244-8018

*Hart*  
*Saman*  
*Barcel*  
*Kane*

RE: CMS-1501-P: Medicare Program Changes to Hospital Payment for 2006  
Payment Rates for AC 674: Prostate Cancer Cryosurgery

Dear Dr. McClellan

The Federal Register, has disclosed that you are planning to reduce hospital reimbursement rates for outpatient Cryosurgery.

I believe your action will retard the availability of this Primary/Minimally Invasive and Cost Effective Procedure, applicable to the vast majority of prostate cancer patients, Staged T-1, T-2 & T-3, as well as, the salvage of failed Radiation procedures, Staged T-1, T-2 & T-3. (Note: T-3 cancer is outside the capsule, but within the soft bed of tissue around the prostate).

My name is Richard Seaman, a Stage T-3 Prostate Cancer Survivor, a Retired Engineer, Business Management Consultant, and an American Cancer Society Prostate Cancer Speaker. I was initially offered radiation (seed with EB) and denied a Radical. Spent 6 months, on drugs to down-sizing an oversized prostate, (to accommodate the radiation seed procedure) and

I am very thankful to have been denied the Radical Procedure..

Using a copy of my medical file, I applied my Engineering and Management skills, to talk with doctors, to understand all the treatment options. I reviewed prostate medical outcome reports, and further investigated each of the available PC Procedures.

I Qualified for All of them and FOUND Cryosurgery.

See my attached Findings.

Sincerely

*Richard Seaman*

Richard Seaman

cc: James L. Hart, Deputy Director

## My Findings:

From an Engineering standpoint, a computer assisted cryogenic freezing is a Programmed, Logical and Lethal Destruction (Rupture) of Cancer Cells.

Thermocouple monitoring in and around the prostate, along with Ultrasound imaging, made perfect technical sense, along with a Urethral Warmer.

Found the procedure was Medicare & FDA Approved. Survival data was comparative to the other procedures. Cryo Survivors, confirmed that my Cryo findings were real. They were up and around within a few days and returned to normal, more laborious, efforts in a week. Also found the Cryo "Downside Effects" were relatively minimal, by comparison to other procedures, except for impotence (which is possible in all the procedures, but was less of a consequence to my wife.).

Note: Cryo, has a 50% probability of potency recovery, over a few years. (More Extensive Biopsy evaluations, have proven that Partial or Focal Cryosurgery can get the cancer and be effective in maintaining potency.)

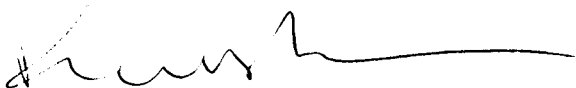
It has taken years for doctors and hospitals to truly understand that Cryosurgery is applicable to the broad range of Prostate Cancer diagnoses (T-1, T-2 & T-3).

Found it is also, a cost effective alternative. The last few years has seen a growing number of hospitals, providing Cryotherapy, as a viable, cost effective, alternative, for their Doctors to apply to Prostate Cancer.

In a time when Medicare dollars need to be applied more broadly, the analysis of the procedure, as well as, follow-up costs, needs to be encouraged. Cost control of any segment of a procedure, needs to be evaluated in the context of the total cost, including any follow-up, rather than a particular element of cost.

Technology is positioned to make significant technical and cost effective advancements, in medical procedures. I trust that Medicare sees the advantages in preserving the growing number of hospital facilities and Medical Plans, that have come to recognize the merits and cost effectiveness of the Cryosurgery procedure, in providing rapid recovery, minimal, if any, side effects and reduced incidences of patient follow-up problems.

Sincerely,



Richard Seaman, Prostate Cancer Survivor & Advocate/Speaker



Valley Baptist  
Health System

2101 Pease Street  
P.O. Drawer 2588  
Harlingen, Texas 78551

August 8, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P.  
P.O. Box 8016  
Baltimore, MD 21244-8018

Comment on Medicare Program; Proposed Changes to the Hospital Outpatient  
Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Page 42742 "Observation Services"

We support the removal of G0244, G0263, G0264 and the proposed addition of GXXXX and GYYYY. The introduction of these two codes represents a simplification of the observation reporting process. In addition, we agree with shifting determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the OPPS claims processing logic. This represents a tremendous decrease in the administrative burden for hospitals.

Sincerely,

Cathy Mezmar RN, MSN  
APC Coordinator

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Observation

AUG 15 2005

Hart  
Samaew  
Kane  
Bazell